RNEC

**GOV-01** **Version number (1.0)** **Effective date (01 Jun 2026)**

# Standard Operating Procedure (SOP) of SOPs

**Definitions**

- **SOP**: Standard Operating Procedure; a written document describing standardised set of instructions and methods for performing specific functions.
- **SOP Master Log**: An official RNEC registry documenting all SOPs, titles, numbers, versions, effective dates, and retirement dates.
- **Version control**: A documented system to track changes, updates, and approval history of SOPs, ensuring that only the latest approved SOP is in use.
- **Revision**: Modifications made to an existing SOP, including minor edits, major updates, additions, or restructuring.
- **Obsolete SOP**: An outdated SOP no longer approved for use.
- **Effective Date**: Date on which an SOP becomes operational

## 1. Purpose

This SOP establishes clear procedures and framework for developing, reviewing, revising, approving, distributing, controlling, distributing, implementing, archiving, and controlling versions of all SOPs used by the Rwanda National Research Ethics Committee (RNEC). This Master SOP ensures consistency, transparency, accuracy, accountability, regulatory compliance, and high-quality functioning of RNEC.

## 2. Scope

This SOP applies to:

- All RNEC members, Management Committee, Secretariat and Administrative staff
- All individuals involved in SOP drafting, reviewing, updating, approving, and storage
- All operational processes requiring written SOPs, including review procedures, membership selection, training, communication, monitoring, quality assurance, and documentation
- All RNEC new SOPs, revisions of SOPs, and SOP retirements

## 3. Policy Statement

RNEC requires:

(1) All operational procedures to be documented in approved SOPs
(2) All SOPs to follow a consistent structure and format
(3) SOPs to be reviewed every **three (3)** to **five (5) years** or earlier if legal and regulations change
(4) Only approved versions may be used in operations
(5) Obsolete SOPs must be removed from circulation and archived

## 4. Structure and Format of RNEC SOPs

All RNEC SOPs must follow a standard format and include:

(1) RNEC logo
(2) SOP category and number
(3) Version number
(4) Effective date
(5) Title
(6) Definitions
(7) Purpose
(8) Scope
(9) Roles and Responsibilities
(10) Procedures (step-by-step)
(11) Documentation and Records
(12) Related Documents (Forms and Templates)
(13) Legal and Regulatory Reference
(14) Revision History

Formatting requirements:

(1) Use consistent font and layout across all SOPs.
(2) Apply uniform numbering across all SOPs.
(3) All SOPs must include a footer (*RNEC Controlled Document - Do Not Duplicate Without Authorisation*) with page number.

## 5. Roles and Responsibilities

- **RNEC Chairperson**: Provides oversight for SOP creation and implementation, approves final SOP versions, ensures SOP alignment and compliance with laws and policies
- **RNEC Secretariat**: Coordinates SOP lifecycle, drafting, formatting, circulation, version control and archiving. Maintains the Master SOP Log and ensures dissemination, distribution of all SOPs and organise SOP training
- **Lead Author**: Drafts and revises SOPs, incorporates feedback, and ensures technical accuracy
- **RNEC Members**: Review draft SOPs, provide technical and ethical inputs, provide feedback, approve final versions, and adhere to current approved SOPs
- **Principal Investigators (Indirect)**: Use and follow RNEC SOPs relevant to their role during submission or reporting processes.

## 6. Procedures of SOP Development

### Step 1. Identification of Need

SOPs may be initiated when:

- New legal and regulatory requirements, or policies emerge
- A new RNEC process or activities introduced
- Research trends in Rwanda require new procedures (e.g., genomic, biobanking, AI, etc.)
- Institutional or existing processes change
- Gaps or inconsistencies are identified during monitoring or audits
- International guidance (e.g., CIOMS, ICH-GCP) is updated
- National or international regulations change
- RNEC members request clarification of processes

### Step 2. Decision on the Need and Assignment

- The full board meeting approves the identified need of SOP revision
- The full board meeting decide whether the draft will be prepared by the Secretariat or designate RNEC member(s) or engage an expert
- The Chairperson and/or the RNEC Secretariat assign the Lead Author or a subcommittee of 2-3 members to drafting or updating the SOP

### Step 3. Drafting the SOP

The Lead Author, Secretariat or engaged Expert must:

- use or follow the official standardised RNEC SOP template
- incorporate applicable laws, guidelines and align SOPs with national and international ethical provisions
- ensure clarity, accuracy, and practicality of SOPs
- consult relevant stakeholders
- include flow diagrams or annexes where useful
- avoid contradictions with existing RNEC SOPs

### Step 4. Internal Review and Incorporation of Feedback

Draft SOPs undergo review by RNEC Secretariat, selected RNEC members and/or Legal specialists

- Draft circulated to RNEC Chair,person and RNEC Members
- Comments are collected by the secretariat and submitted to the Lead Author
- The Lead Author revises the draft and Incorporate the Feedback based on reviewers' comments
- The Internal Review must ensure alignment with other existing SOPs

### Step 5. Approval and Approval Meeting

**The Approval Authority**: The RNEC Chairperson is the final approving authority unless delegated

- Lead Author submits final draft
- Final draft SOP is presented and reviewed during an RNEC full-board committee meeting
- Approval is based on majority vote
- Changes are documented in the revision history
- SOP receives a version number and the effective date
- Details of approval documented in meeting minutes
- Chairperson reviews and signs the approval page of the SOP

#### Step 6. SOP Numbering and Master Log Entry

Each SOP is assigned:

- A category code (e.g. **GOV** for Governance and Administration, **REV** for Review Procedures, **QA** for Quality Assurance)
- A unique SOP number within the category (*e.g., RNEC-GOV-01*)
- A version number
  - Version 1.0 = Initial SOP
  - Version 1.1 = Minor edits
  - Version 2.0 = Major revision

The SOP is entered into the Master SOP Log, maintained by the Secretariat

### 7. SOP Distribution and Implementation

Upon approval:

- Secretariat distributes the SOP electronically to all RNEC members and staff
- The SOP is posted on the RNEC website and official online portal if appropriate
- Replace previous versions in all repositories (*digital and physical*)

Implementation:

- Secretariat ensures removal of old versions and training on new/revised SOPs
- Training or orientation should be provided, especially for SOPs related to review processes, SAEs, or complex designs (e.g., multi-site trials)
- Ensure that only the version marked *CURRENT* in the Master Log will be used (*Controlled copy*)
- Effective date must be clearly stated, in addition to approval date and version number

### 8. SOP Review and Updating

(1) Scheduled Review: All SOPs must be reviewed every 3–5 years
(2) Triggers for Revision:
  - Changes in national regulations (e.g., regulatory or policy updates, new laws)
  - Changes in operational processes or online submission platform
  - Implementation challenges or inconsistencies
  - Audit findings from MoH Inspectorate or external agencies
  - Feedback from RNEC members, Secretariat, or external bodies
  - User feedback indicating ambiguity
  - New processes or technologies emerge
  - Updates to international guidance (CIOMS/ ICH-GCP)

(3) Revision Process:
  - Secretariat coordinates drafting the revised version (*tracked changes required*)
  - Circulate for comments to Chairperson and members
  - Present revised SOP during an RNEC meeting
  - Approval documented in minutes
  - Assign new version number (e.g., from v1.0 ➡ v2.0)
  - Replace old SOP in all systems and update Master Log
  - Archive superseded version (*do NOT delete*)

(4) Documentation: Revision history and change logs must be updated
(5) Revised SOPs follow the same approval process as new SOPs

### 9. Version Control and Archiving

(1) Only the current approved SOP must be available for use
(2) Obsolete SOPs must be archived with labels: 'Archived – Not for Use'
(3) RNEC maintains a Master List with: SOP title, number, version, dates, and status
(4) Archived SOPs should be retrieved for audits or inquiries
(5) An SOP may be retired when:
  - It is replaced by a newer SOP
  - The associated process is no longer implemented (e.g., paper submissions replaced by online systems)
  - Regulatory changes make the SOP obsolete

(6) Retirement procedure:
  - Chairperson endorses retirement
  - Secretariat updates Master SOP Log with retirement date

- Document retirement date in Master Log
- SOP moved into the Retired SOPs Archive
- Notify all RNEC members

## 10. SOP Training Requirements

- All new RNEC members must undergo SOP orientation during induction
- Annual refresher training on key SOPs (protocol review, SAEs, amendments)
- Training attendance recorded and archived.
- Secretariat ensures training materials align with current SOPs

## 11. Quality Assurance

- Conduct annual SOP compliance audits
- Verify that reviewers follow SOPs during ethical review
- Internal audits to check if practices follow written SOPs.
- Ensure RNEC practices meet Rwanda National Guidelines and international standards
- A Corrective and Preventive Action (CAPA) plan must be developed when noncompliance is found

## 12. Documentation and Records

The following records must be maintained:

- SOP drafts
- Approved versions
- Revision history logs
- Approval signatures
- Distribution lists
- Training records

The Secretariat ensures that:

- All pages stamped RNEC Controlled Document
- Only Secretariat may edit and modify master files.
- Ensure correct version appears on the website or portals

## 13. Record Keeping and Archiving

RNEC archiving requirements:

- SOPs stored in the RNEC secure digital repository
- Password-protected access for Secretariat and Chair
- Hard copies stored in secured and locked cabinets
- Master SOP Log must be retained indefinitely
- All SOP versions archived for **at least 10 years**
- Approval meeting minutes stored securely and indefinitely
- All SOPs dated, signed, and version-controlled
- Retired SOPs stored separately in a labelled archive

## 14. References and Ethical Framework

(1) Law N° 015/2022 of 29/06/2022 relating to research on a human being (View/Download).
(2) Ministerial Order N° 002/MoH/2023 of 21/03/2023 relating to Rwanda National Research Ethics Committee on a human being (View/Download).
(3) Law N° 003/2018 of 09/02/2018 Establishing the Rwanda Food and Drugs Authority, and Determining its Mission, Organization and Functioning (View/Download).
(4) Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Participants (2024) (View/Download)
(5) CIOMS - International Ethical Guidelines for Health-related Research Involving Humans (2016) (View/Download)
(6) ICH - Guideline for Good Clinical Practice E6 (R3) View here
(7) WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (2011) (View/Download)
(8) RNEC Ethical Guidelines (View/Download)

## 15. Revision History

| Version | Date | Summary of changes |
|---|---|---|
| **1.0** | **11-05-2026** | First RNEC SOP on SOP Development, Review, Updating, and Version Control. |